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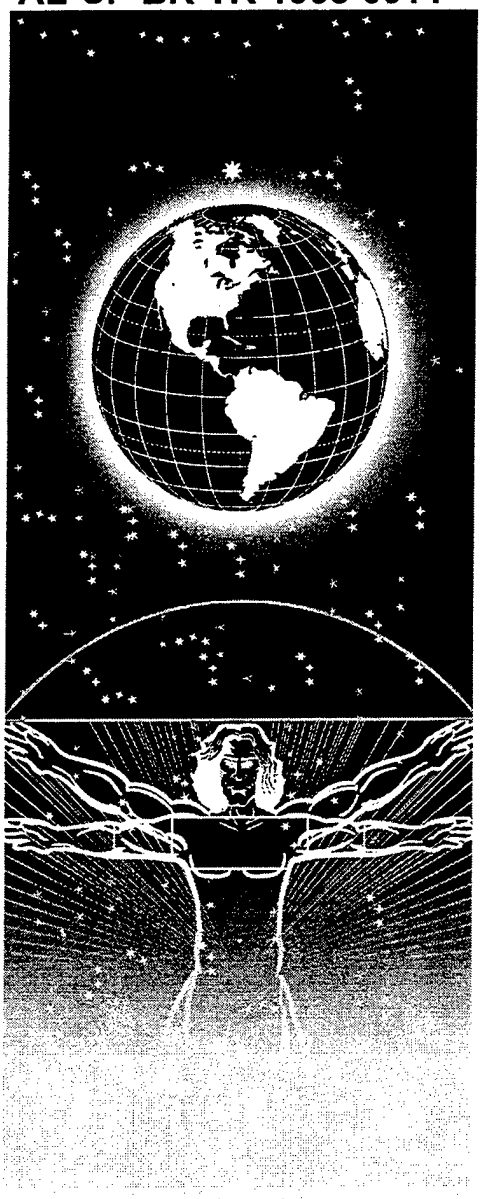

UNITED STATES AIR FORCE
ARMSTRONG LABORATORY

TESTING AND EVALUATION OF THE BCI 3304 PULSE OXIMETER

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NOTICES

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The BCI International, Inc., Model 3304, Pulseo Oximeter is a portable pulse oximeter that measures SpO2 and pulse through the use of either a disposable probe or a reusable finger probe. The unit operates on 115 VAC/60 Hz and an internal rechargeable battery pack

14. SUBJECT TERMS

BCI aircraft medical equipment
3304 approved aeromedical
airworthy Pulse Oximeter

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TESTING AND EVALUATION OF THE BCI 3304 PULSE OXIMETER

BACKGROUND

BCI International requested that Armstrong Lab evaluate the 3304 pulse oximeter system for use on board USAF aeromedical evacuation aircraft. Components of the 3304 system include the 3304 pulse oximeter, serial number 260210572, a 12VDC power supply (catalog number 1611), and a reusable finger probe (serial number 260217312). The 3304 pulse oximeter, the model 1611 power supply, and the reusable finger probe were tested for airworthiness. Throughout this report "3304" refers to the 3304 pulse oximeter and the term "3304 system" refers to 3304 pulse oximeter, the model 1611 power supply, and the reusable finger probe.

DESCRIPTION

The 3304 is a portable pulse oximeter that measures SpO_2 and pulse through the use of either a disposable probe or a reusable finger probe. SpO_2 is defined as the arterial O_2 saturation measured by a pulse Doppler technique The disposable probe comes in a variety of sizes to fit adults to neonates and may be used at various points on the patient's body. The rechargeable internal battery lasts 4.5 hour nominal use without recharging. A 115 VAC/60 power supply is used to either recharge the battery or operate the unit continuously while the battery is trickle charged. Any time the 115 VAC/60Hz power supply is connected, the battery is maintained even if the 3304 is turned off.

The 3304 has SpO_2 and pulse rate numeric LED displays, an eight-segment LED pulse strength bar graph, artifact light, search light, probe light, low batt light, and alarm silenced light. There is a power light that indicates the 115 VAC/60Hz power supply is attached and the 3304's battery is charging.

The 3304 has controls for on/off, alarm volume, pulse volume, volume up and down, I.D. clear, alarm silence, and alarm select. The operator can set alarm and pulse volume to individual preference. The "I.D. clear" is used to reference multiple patients each time the button is pressed, or the stored patient data can be erased and the patient counter reset.

The 3304 has two modes of operation: Clinician and Home-use. The Clinician mode is for use by health care professionals, the Home-use mode permits the home-use caregiver to monitor a patient at home and also record the data for later analysis.

General Specifications Of The BCI 3304 Pulse Oximeter

Size	216 mm (8.5 in)	82 mm (3.24 in)	140 mm (5.5 in)
Weight	850 grams (30 ounces)		
SpO2 Range	0% - 100%		
Pulse Rate	30 - 254 BPM		

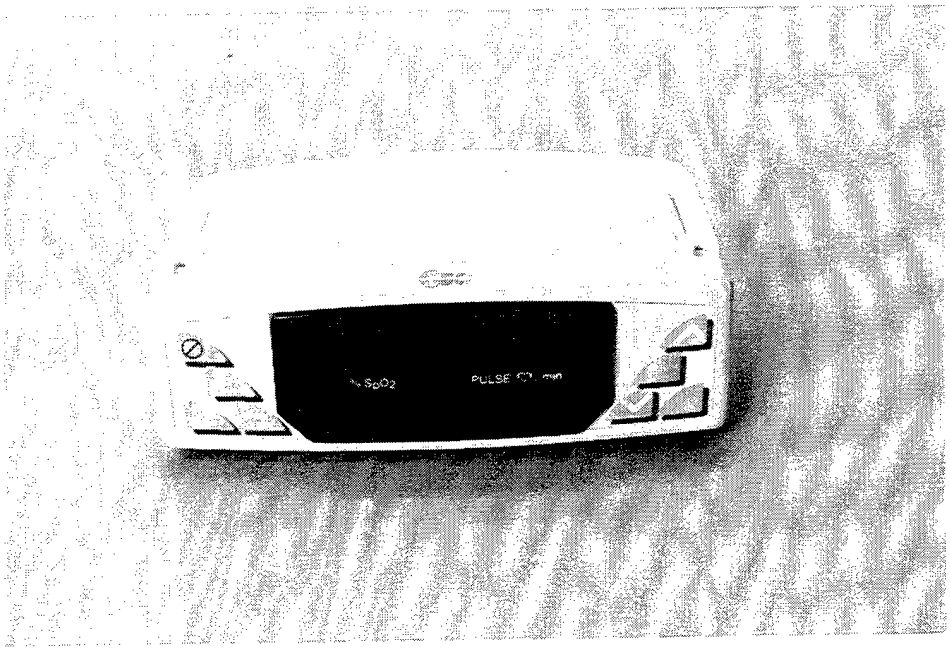


Figure 1. BCI 3304 System

PROCEDURES

Test methods and performance criteria were derived from various military standards (1-3 & 8-9), nationally recognized performance guidelines (4 & 7), and manufacturer's literature (5). The Aeromedical Research Procedures Guide describes additional safety and human interface issues to be considered during equipment testing (6). A test setup and performance check were developed specifically for this product to verify proper functioning of the equipment under various test conditions. Unless otherwise noted all testing is conducted and monitored by Aeromedical Research personnel assigned to the Systems Research Branch (CFTS), Crew Technology Division, Armstrong Laboratory, Brooks AFB, TX.

The device was subjected to various laboratory and in-flight tests to observe and evaluate its performance under anticipated operational conditions.

1. Initial Inspection

2. Vibration

3. Electromagnetic interference (EMI)

4. Thermal/Humidity Environmental Conditions, Encompassing:

    a. Hot Operation

    b. Cold Operation

    c. Humidity Operation

    d. Hot Temperature Storage

    e. Cold Temperature Storage

5. Hypobaric conditions

    a. Cabin Pressure/Altitude

    b. Rapid Decompression to Ambient Pressure

6. Airborne Performance

INITIAL INSPECTION AND TEST PREPARATION

a. The BCI 3304 system was inspected for quality of workmanship, production techniques, and possible damage incurred during shipment.

b. The BCI 3304 system was checked to ensure it met basic human factors design requirements as outlined in Mil STD 1472 (3).

c. A test setup and performance check were developed to evaluate the BCI 3304 systems operation in accordance with manufacturer/customer specifications throughout the various testing conditions.

TEST SETUP

The 3304 was connected to the BCI simulator model number 1606 serial number 430038041. The displayed values should be 97-99% for SpO_2 and 79-81 BPM for pulse. The normal displayed values were 98% for SpO_2 and 79 BPM for pulse.

BCI 3304, Test Set-Up

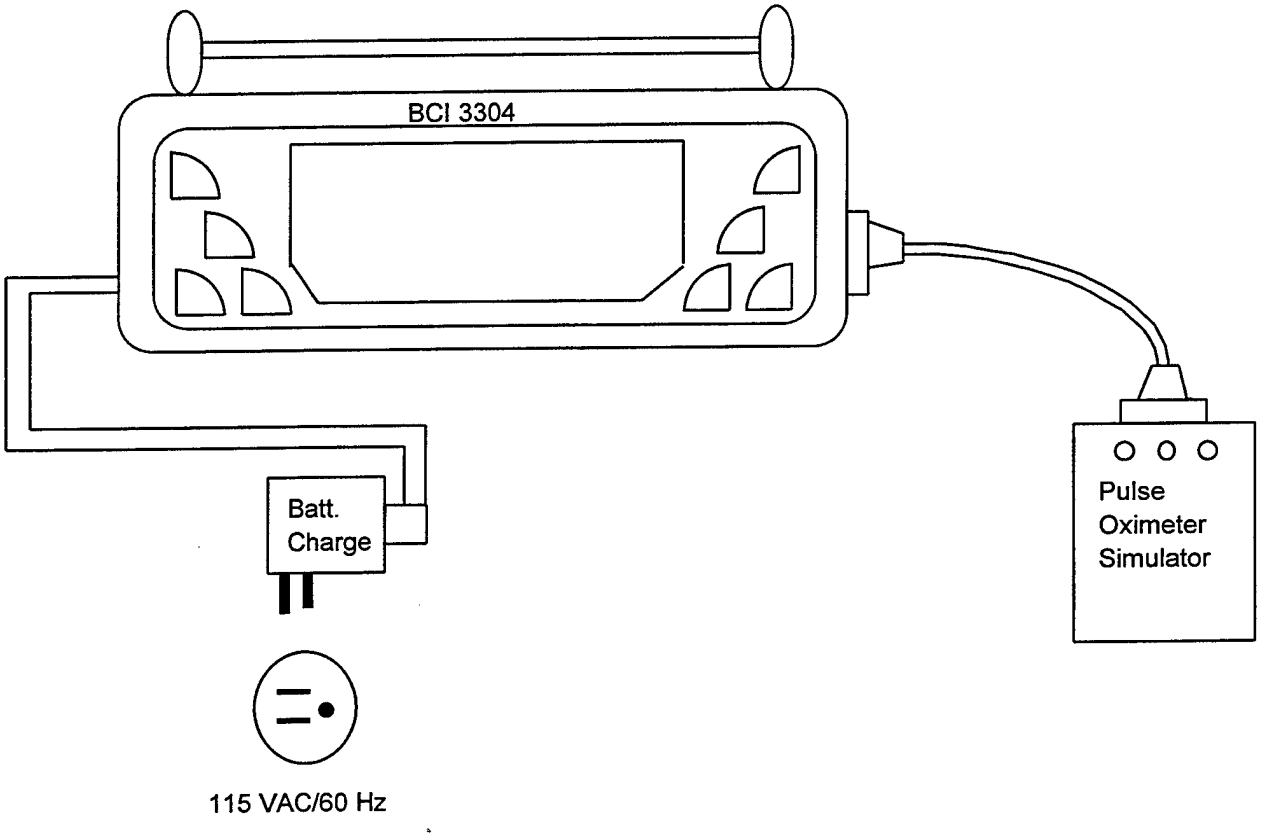


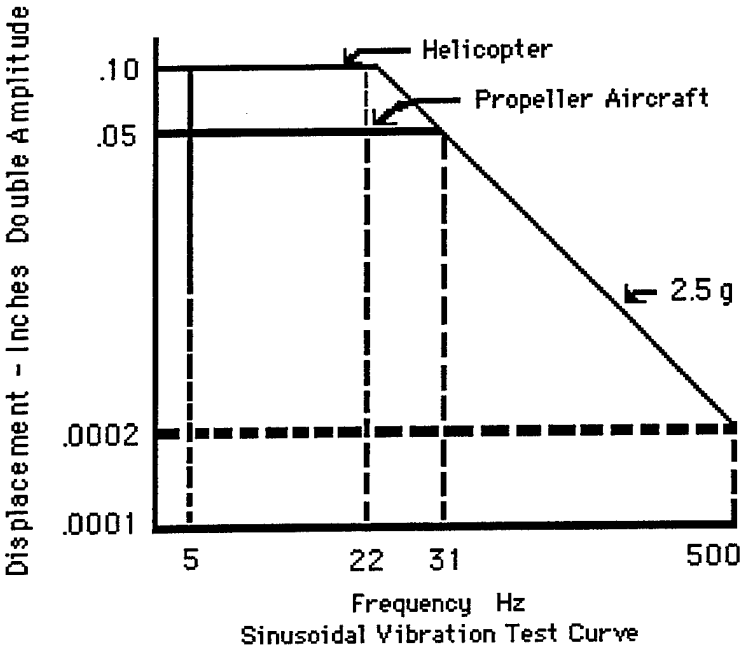
Figure 2. Test Setup

PERFORMANCE CHECK

The 3304 was connected to the power supply and monitored to determine if the power light was functioning. The displayed values of the 3304 connected to the BCI simulator were recorded. The probe was placed on a human finger to determine if the displayed values would change appropriately.

VIBRATION

Vibration testing is critical to determine "the resistance of equipment to vibrational stresses expected in its shipment and application environments" (2). Testing was conducted on a Unholtz-Dickey Corporation Vibration Test System, amplifier model SA30 and shaker model R16W. This testing involved a set of operational tests performed along each of the BCI 3304 system's three axes - X, Y, and Z, with the BCI 3304 system components mounted on the NATO litter segment on the vibration table as they would be in the aircraft. The BCI 3304 was subjected to vibration curves that are derived from Mil STD 810E, Category 10, Figures 514.4-16 and 514.4-17 (Figure 3).



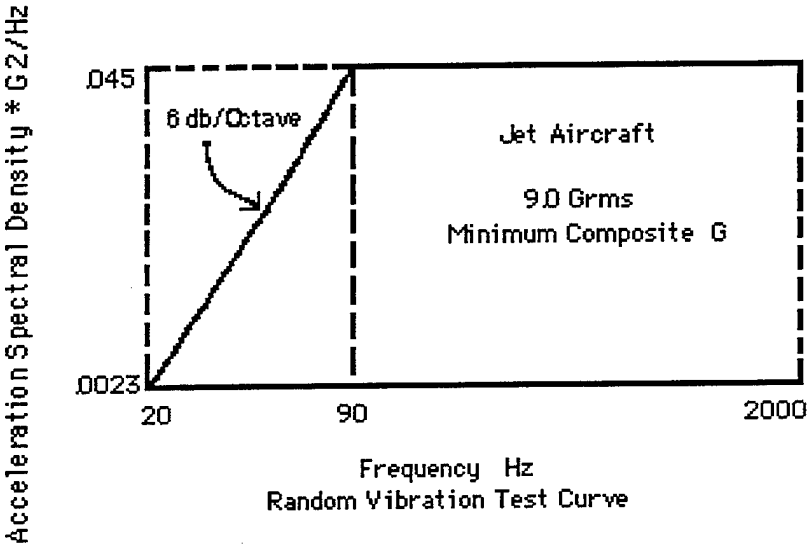


Figure 3. Aeromedical Research Vibration Curves

ELECTROMAGNETIC COMPATIBILITY

Electromagnetic compatibility is a primary concern on USAF aeromedical evacuation aircraft. Ensuring the safety of everyone on board is the driving factor in assessing the effects of excessive electromagnetic emissions and their influence on aircraft navigation and communication equipment. Medical devices may also be susceptible to electromagnetic interference (EMI) fields generated by the aircraft equipment or other medical devices.

The BCI 3304 system was evaluated for compliance with Mil STD 461D (1). WL/AASW, Wright Patterson AFB performed the evaluation in their electromagnetic compatibility facility. ASC/ENAI, Wright-Patterson AFB, evaluated the electromagnetic compatibility data and determined the airworthiness of the medical device. Specific tests conducted were as follows:

a. Radiated Emissions (RE-102), "Radiated Emissions, Electric Field, 10 kHz to 18 GHz.": For Air Force aircraft applications, radiated emissions were tested in a narrower range of frequencies from 2 MHz - 1 GHz. This test measured the amount of EMI emitted by the system under test during its operation.

b. Conducted Emissions (CE-102), "Conducted Emissions, Power Leads, 10 kHz to 10 MHz.": For Air Force aircraft applications, conducted emissions were tested throughout the entire band of 10 kHz - 10 MHz. This test measured emissions reflected back down the power lines by the system under test.

c. Radiated Susceptibility (RS-103), "Radiated Susceptibility, Electric Field, 10 kHz to 40 GHz.": for Air Force aircraft applications, radiated susceptibility was tested in a narrower frequency range from 30 MHz - 12.4 GHz at the following field strength levels: 20 V/M below 1 GHz and 60 V/M above 1 GHz (field strength values from Table IV, category Aircraft Internal, of 461D). This test evaluated the resistance of the system under test to set levels of EMI generated by both internal and external aircraft antennas.

d. Conducted Susceptibility (CS-101), "Conducted Susceptibility, Power Leads, 30 Hz to 50 kHz.": For Air Force aeromedical aircraft applications, conducted susceptibility was tested throughout the entire frequency band, from 30 Hz to 50 kHz. This test determined the ability of the system under test to withstand "ripple voltages associated with allowable distortion of power source voltage wave forms."

e. Conducted Susceptibility (CS-114), "Conducted Susceptibility, Bulk Cable Injection, 10 kHz to 400 MHz.": For Air Force aeromedical aircraft applications conducted susceptibility was tested throughout a narrower portion of the frequency band, from 10 kHz to 200 MHz. This test determined whether "simulated currents

which were developed on platform cabling from electromagnetic fields generated by antenna transmission both on and off the platform" would affect the system under test.

f. Conducted Susceptibility (CS-115), "Conducted Susceptibility, Bulk Cable Injection, Impulse Excitation": This test evaluated the resistance of the system under test to the "fast rise and fall time transients that may be present due to platform switching operations and external transient environments such as lightning and electromagnetic pulse."

The 3304 was tested both on battery and line power. The alarms were triggered when possible but, due to testing constraints, the alarms could not be on continuously.

THERMAL/HUMIDITY ENVIRONMENTAL CONDITIONS

Extremes of temperature and humidity testing are critical to determine if aeromedical equipment can be stored and operated during severe environmental conditions "without experiencing physical damage or deterioration in performance" (2). Extreme environmental conditions can have numerous detrimental effects on medical equipment including changes in material characteristics and material dimensions, possible overheating, changes in electronic component characteristics, and electronic or mechanical failures due to rapid water or frost formation.

Testing was conducted in the Armstrong Laboratory environmental chambers. The 3304 system was placed in the chamber. The power supply was plugged into an extension cord that was run out of the chamber through a port in the chamber wall, sealed with a precut sponge plug. The reusable finger probe was placed in the environmental chamber and the plug run outside of the chamber through another port sealed like to AC power cord. A 5-ft extension cord was connected to the 3304 and run out of the chamber through the same port as the finger probe. For most of the test the BCI simulator was connected to the 3304. At random times during the test the reusable finger probe was connected to the 3304 and placed on a human finger. This protocol insured that the values displayed were actually changing. For operational tests, the 3304 system was monitored continuously and a performance check was performed every fifteen minutes. For storage tests, the 3304 system was placed in the chamber and remained inoperative throughout the test. The following describes the conditions of the environmental tests performed

a. Humidity: 94 +/- 4% RH, 85 +/- 3.6°F (29.5 +/- 2°C) for 4 hours

b. Hot Temp Operation: 120 +/- 3.6°F (49 +/- 2°C) for 2 hours

c. Cold Temp Operation: 32F +/- 7.2°F (0 +/- 2°C) for 2 hours

d. Hot Temp Storage: 140 +/- 3.6°F (60 +/- 2°C) for 6 hours

e. Cold Temp Storage: -40 +/- 3.6°F (-40 +/- 2°C) for 6 hours

HYPOBARIC CONDITIONS

Testing was conducted in the Armstrong Laboratory research chambers.

a. Cabin pressure/Altitude: Altitude testing is critical for aeromedical evacuation equipment due to the potential effects of barometric pressure changes on the equipment. A majority of the aircraft, which are characterized as opportune aircraft available for use in aeromedical evacuation, pressurize their cabin atmosphere to barometric pressures equivalent to 8,000 - 10,000 feet above sea level. The differences in pressures can be critical to the effective operation of some medical equipment. Altitude testing consisted of operating the 3304 system while ascending from ground level to 10,000 ft (maintaining altitude for one hour) and then descending back to ground, at rates of 5,000 ft/min, while stopping at 2,000 ft increments for performance checks.

b. Rapid Decompression Testing: Rapid decompression is caused by the loss of aircraft cabin pressurization and subsequent pressure equalization with ambient atmospheric pressures. It is important to determine how medical equipment will function during and after such a decompression to ensure that it will not endanger a patient, the aircraft personnel, or the aircraft itself. The 3304 system was operated inside the rapid decompression test chamber as the chamber was pressurized to an equivalent altitude of 8,000 ft (2,430 meters). Then, the chamber altitude was brought to 45,000 ft. (13,716 meters) over a period of 60 seconds, held at 45,000 ft for a few minutes, and then returned to ground level at a rate of 10,000 - 12,000 ft/min. The test was repeated two more times with decompression periods of 7 seconds and 1 second, respectively. The 3304 system was monitored throughout the series of decompressions, including performance checks each time the unit returned to ground. The simulator equipment remained outside the chamber. Connections for the simulator and the power supply for the 3304 were run through putty-sealed access ports in the chamber walls.

AIRBORNE PERFORMANCE

Airborne performance evaluations are a cost-effective and invaluable means of validating a piece of equipment's clinical and operational suitability under actual operating conditions. By carefully evaluating medical equipment items in their actual environment, Aeromedical Research ensures that all pertinent patient care issues are

adequately addressed by the test protocols. Safe and reliable operation of this medical equipment support device is the primary goal of the in-flight evaluation and forms the basis for subsequent recommendations to the users.

This phase of testing was conducted by an aircraft-qualified aeromedical flight nurse and aeromedical research technicians on board a C-9 aeromedical evacuation mission. The 3304 was carried by the Aeromedical Research technician and the reusable finger probe was placed on the technician's finger. Human factors characteristics, securing methods, and equipment setup times and location were also evaluated.

EVALUATION RESULTS

INITIAL INSPECTION

Initial inspection revealed no manufacturing defects. The unit performed to the manufacturer's specification. The unit has an all plastic case; therefore, no electrical safety tests were done.

VIBRATION

During vibration the main board ribbon cable connector came loose. This connector is part of the ribbon cable that connects the main board to the display board. The connector was reconnected and a small amount of RTV was used to secure it. During further testing the leads on capacitor C3 on the display board broke loose. The capacitor was resoldered. A small drop of RTV was used to secure the capacitor to the board. Testing was completed. The company was notified of the capacitor failure and the loose connector.

ELECTROMAGNETIC COMPATIBILITY

The 3304 system met all limits for emissions and susceptibility testing except for CS-115. ASC/ENAI Wright-Patterson AFB issued a letter dated 17 Dec 1996 stating that the emissions from the system were within limits and the system was certified for use during all phases of flight on all Air Force aircraft. Aeromedical Research Brooks AFB issued a letter dated 18 Feb 1997 stating that the system is approved for use but warning the users that the system may experience temporary failure when operating near impulse excitation; e.g., radar sweeps.

THERMAL/HUMIDITY ENVIRONMENTAL CONDITIONS

The 3304 system operated satisfactorily during all five phases of thermal/humidity testing.

HYPOBARIC CONDITIONS

1. Cabin pressure/Altitude: The 3304 system experienced drifting values when it was connected to the simulator and to human subjects using the reusable finger probe at altitudes of 7,000 ft and higher. Discussions with the manufacturer indicated that changing the averaging settings should help the problem. Following the instructions in the Clinician's Operation Manual the averaging was increased from the default value of 8 to a new value of 16 for the SpO_2 and pulse averaging. This new setting stopped the drifting values.

2. Rapid Decompression: The 3304 system operated satisfactorily following each decompression.

AIRBORNE PERFORMANCE

The in-flight evaluation of the 3304 system was performed on a C-9 aeromedical evacuation mission. The handle on the 3304 is designed to fit on a round handle. The size of the mounting hole does not permit use on a NATO litter. Other operations were normal.

SUMMARY

Aeromedical Research found the BCI 3304 to be acceptable for use on all U.S. Air Force aeromedical evacuation aircraft. The unit should be used strictly as a trend indication device. Several problems noted during vibration testing should be corrected by the company. The following recommendations and warnings accompany the airworthiness approval of the 3304 system.

a. **The AC power supplies for the BCI 3303 and 3304 are NOT INTERCHANGEABLE.** The power plugs on the pulse oximeters are the same, but the power supplies are not. Be sure you have the right power supply for the unit. Destruction of the 3304 or the power supply will result from use of the wrong supply.

b. The unit may fail to operate properly when exposed to impulse excitations e.g. radar sweeps. The unit should recover as soon as the signal strength decreases.

c. The unit readout values may drift up and down at altitudes above 6,500 ft. The correction of this may involve changing the averaging factors for SpO_2 and pulse. This drift may be corrected by following the instructions in the operations manual.

REFERENCES

1. Mil-STD 461D, Electromagnetic Emission and Susceptibility Requirements for the Control of Electromagnetic Interference.

2. Mil-STD 810E, Environmental Test Methods and Engineering Guidelines.

3. Mil-STD 1472, Human Engineering Design Criteria for Military Systems.

4. Emergency Care Research Institute (ECRI).

5. BCI International, 3304 System, Operator's Manuals.

6. Aeromedical Research Procedures Guide, Internal Operating Instruction, Systems Research Branch, Armstrong Laboratory.

7. National Fire Protection Agency (NFPA) 99, Health Care Facilities Code.

8. AFI 41-203, Electrical Shock Hazards.

9. AFI 41-201, Equipment Management in Hospitals.

APPENDIX

MANUFACTURER'S SPECIFICATIONS OF THE BCI INTERNATIONAL 3304 SYSTEM

SPECIFICATIONS

General

Size	216 mm x 82 mm x 140 mm (8.5 in wide x 3.24 in high x 5.5 in deep)
Weight	850 grams (30 ounces) including battery
Power	Internal rechargeable battery, wall mount AC power supply
Environmental	Temperature (Operating) 0 - 40°C (32 - 104°F) (Storage) -40 - 75°C (-40 - 167°F)

DISPLAYS, INDICATORS, & KEYS

SpO_2	3-digit LED display, 10.9 mm (0.43 inches) high
Pulse Rate	3-digit LED display, 9.5 mm (0.375 inches) high
Pulse Strength	Logarithmically scaled 8-segment LED bar graph
PROBE	Probe alert indicator
BATT	Low battery indicator
SILENCE	Alarm and alert tone silenced indicator
ALARM	Alarm indicator
ARTIFACT	Indicates the presence of motion artifact
SEARCH	Indicates the monitor is looking far a pulse

Keys	Nine control keys provided
Brightness displays	Adjustable brightness of SpO_2, pulse rate, and bar graph
Power	Indicates oximeter connected to AC power

SpO_2

Range	0 - 100%
Accuracy	+/- 2% at 70 - 100% +/- 3% at 50 - 69%
Alarm Limits	High 100 - 50% and off in 1% steps Low 50 - 99% and off in 1% steps
Averaging	4, 8, or 16 pulse beat average

PULSE RATE

Range	30 - 254 BPM
Accuracy	+/- 2% at 30 - 254 BPM
Alarm limits	High 250 - 5 BPM and off in 1 BPM steps Low 5 - 250 BPM and off in 1 BPM steps
Averaging	8 or 16 second average

ALARM INDICATORS

Two-tone audible alarm with user-adjustable volume and two-minute or indefinite alarm silence. Corresponding numeric display flashes

PROBE ALERT INDICATOR

Single-tone audible alarm with same volume and silence as alarm tone

PRINTER OUTPUT

SpO2 and pulse rate can be printed every five (5) seconds (data log). Data saved every four (4) to thirty (30) seconds can be printed (trend).

BATTERY

Type	Internal rechargeable lead acid; not user replaceable
Charge Time	Fully charges in about 6 hours
Use Time	Approximately 4.5 hours continuos use
Indicators	LO BATT indicator light when about 30 minutes of battery use remains

AC CHARGER

Wall Mount Style	Input of 105 - 125 VAC 60 Hz, Output 12VDC